

## REMARKS

The present application is directed to methods and compositions comprising mycobacterial DNA for treating cancer. More specifically, the present invention is directed to methods and compositions which contain mycobacterial DNA for the treatment of prostate cancer.

In an effort to facilitate prosecution, Claims 26, 36, 40, 48, 66, 69, 71, 73, 75, and 77 have been amended. Following entry of this amendment Claims 26-50, and 66-78 will be pending in this application. No new matter has been added and support for the amendments is found throughout the specification.

Applicants thank Examiners Angell and Nguyen for taking the time to discuss this application and the March 10, 2004 Final Office Action with applicants' representatives, John K. McDonald and Sima Singadia Kulkarni on Monday March 29, 2004. Pursuant to the Examiners' recommendation, applicants submit the following remarks and request entry of the amendments.

### *Double Patenting*

In the March 10, 2004 Office Action, the Examiner maintained the rejection of Claims 26-56 and 66-68 and also rejected Claims 69-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-30 of United States Patent No. 6,326,357 (hereafter '357) in view of Morales et al., J. Urology, 153:1706-10 (1995) (hereinafter referred to as "Morales."). The rejection was maintained for reasons of record.

In response to the applicants' previously submitted arguments, the Examiner maintained the rejection stating that "all of the references teach mycobacterial compositions that have anti-cancer effects when administered to cancer cells".

In an effort to facilitate prosecution, applicants submit herewith a terminal disclaimer. Accordingly, applicants request reconsideration and withdrawal of the rejection.

*Rejection of Claims 26-56 and 66-68 under 35 U.S.C. 112, first paragraph*

In the March 10, 2004 Office Action, the Examiner maintained the rejection of Claims 26-56, 66-68 and now Claims 69-78 under 35 U.S.C. 112, first paragraph because according to the Examiner, they do not reasonably provide enablement for the full scope encompassed by the claims.

Specifically, the Examiner stated that the claims are not enabled for general (e.g. any route of administration other than direct delivery to the prostate tumor, such as *systemic*) delivery of the claimed composition. The Examiner indicated however, that limiting the claims to administering the mycobacterial compositions directly to the prostate tumor would obviate this rejection.

During the phone conversation on March 29, 2004 with applicants' representatives, the Examiners' recommended incorporation of the language "at the cancer cells" into the relevant claims as a way of addressing and overcoming this rejection. Pursuant to the Examiners' recommendation, applicants have herein amended the relevant claims, and accordingly request reconsideration and withdrawal of this rejection.

*Conclusion*


For at least the above reasons, Applicants respectfully request allowance of claims Claims 26-50, and 66-78 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney.

The foregoing is submitted as a full and complete response to the Office Action mailed March 10, 2004. Applicants respectfully submit that the claims are fully enabled, novel and non-obvious over the cited art. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at

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Respectfully submitted,  
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